DEC 1 0 2003

K033392

510(K) SUMMARY

Date: 10/07/03

Contact Person: David D. Dalise
President/Owner "O" Company, Inc.

Trade Name: (ISI) Immediate Stabilizing Implant
Common Name: Endosseous Screw Implant
Classification Name: Dental Implant Endosseous / Code 76DZE

Substantial Equivalence to: Bicortical Screw K983120 Cleared 7/29/99
LaminOss K982925 Cleared 5/15/99
Altiva K992512 Cleared 11/1/99
Crystal Stabledent K011502 10/22/01

Description of Device: Self-tapping one-piece CP Titanium threaded dental implant, with a roughened surface treatment. Available in 3.25mm, 4.0mm, and 5.0mm diameter, and in lengths of 8mm 10mm, 12mm, 14mm & 16mm.

Indications for Use: The Immediate Stabilizing Implant (ISI) is a one-piece threaded dental implant with the abutment incorporated into the design for a single stage surgical procedure. The implant is intended to be surgically placed in the bone of the upper or lower jaw arches providing support for prosthetic devices resulting in the restoration of the patient's chewing function. Immediate loading can be obtained if implants are rigidly splinted.

Substantial Equivalence: Substantial Equivalence for the Immediate Stabilizing Implant (ISI) is based on the following comparison of a predicate devices such as, **Bicortical Screw Implant #K983120, LaminOss # K982925, Altiva K992512, and Crystal Stabledent K011502.** The design, function, labeling, material composition and intended use are equivalent to these devices currently on the market.

This data supports our determination that the Immediate Stabilizing Implant (ISI) is Substantially equivalent to the Bicortical Screw Implant, LaminOss, Altiva, and Crystal Stabledent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2003

"O" Company Incorporated
Mr. David D. Dalise
President/ Owner
600 Paisano NE Suite A
Albuguerque, New Mexico 87123

Re: K033392
Trade/Device Name: Immediate stabilizing Implant (ISI)
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: October 10, 2003
Received: October 23, 2003

Dear Mr. Dalise:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K033392

Device Name: Immediate Stabilizing Implant (ISI)

Indications For Use:

The Immediate Stabilizing Implant (ISI) is a one-piece threaded dental implant with the abutment incorporated into the design for a single stage surgical procedure. The implant is intended to be surgically placed in the bone of the upper or lower jaw arches providing support for prosthetic devices resulting in the restoration of the patient's chewing function.

Immediate loading can be obtained if implants are rigidly splinted between the mental foramina.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033392